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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,238	08/01/2003	Tilak M. Shah	4179-126	2458
23448 7590 08/27/2007 INTELLECTUAL PROPERTY / TECHNOLOGY LAW PO BOX 14329 RESEARCH TRIANGLE PARK, NC 27709			EXAMINER FIDEI, DAVID	
			ART UNIT 3728	PAPER NUMBER
			MAIL DATE 08/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/633,238

Applicant(s)

SHAH, TILAK M.

Examiner

David T. Fidei

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24, 26-29, 31-33 and 35-38 is/are rejected.
- 7) ☒ Claim(s) 25 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 22, 23, 26, 27, 31, 32, 35 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Matsumoto et al (Pub no. US 2002/0197738). As to claim 22 Matsumoto discloses a collapsible tube Y with a closed distal end defined by bag-like portion 3d and an open proximal end 3a. It is not specific what structural features that integral hinge elements has in the claim and Matsumoto et al discloses a constriction 3c that forms integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body. The body has a substantially uniform diameter along the open proximal end 3a as shown in figure 4.

As to claim 23, 31 and 32, the body has a central axis extending through the closed distal end and the open proximal end that can be considered to define an average cross-sectional area in a direction perpendicular to the central axis where the open proximal end 3a has a cross-sectional area at least as large as the average cross-sectional area since the proximal end 3a of figure 4 is shown as large as any other portion of the tube Y.

As to claims 26 and 35, the integral hinge elements comprises a rigid structure of a constriction 3c.

As to claims 27 and 36, the process by which the tube is formed is of no patentable distinction. A "product by process" claim is directed to the product per se, no matter how actually made, In re Hirao, 190 USPQ 15 at 17(footnote 3). See also In re Brown, 173 USPQ 685; In re Luck, 177 USPQ 523; In re Fessmann, 180 USPQ 324; In re Avery, 186 USPQ 161; In re Wertheim, 191 USPQ 90; and In re Marosi et al, 218 USPQ 289, all of which make it clear that it is the patentability of the final product per se which must be determined in a "product by

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process" claim, and the an old or obvious product produced by a new method is not patentable as a product, whether claimed in "product by process" claims or not. During examination, the patentability of a product-by-process claim is determined by the novelty and non-obviousness of the claimed product itself without consideration of the process for making it which is recited in the claim. In re Thorpe, 227 USPQ 964 (Fed. Cir. 1985), M.P.E.P. § 2113.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 24 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al as applied to claims 22 and 31 above, and further in view of Grant (US Patent no. 5,477,863). The difference between the claimed subject matter and Matsumoto et al resides in a cap matably engageable with coupling structure at the proximal end of the tube. Grant discloses a sample container 11 matably engageable with a cap 12 as shown in figures 2 and 9 as is conventional in the art. It would have been obvious to one of ordinary skill in the art to modify the container of Matsumoto et al by further constructing a cap matably engageable with coupling

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structure at the proximal end of the container as suggested by Grant, in order to retain the sample contents within the container.

6. Claims 28, 29, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al (Pub no. US 2002/0197738). The difference between the claimed subject matter and Matsumoto et al resides in the dimensions of the tube and material used to construct the tube. Matsumoto et al is silent regarding the dimensions and a soft synthetic resin is the only disclosure of material used. As to the former, it has been held that, where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than a prior art device, the claimed device is not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

As to the material used to form the tube, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ conventional materials such as polypropylene, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice, see § M.P.E.P. 2144.06.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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8. Applicant is advised that should claim 23 be found allowable, claim 32 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Allowable Subject Matter

9. Claims 25 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

10. Applicant's arguments, see pages 7-23, filed June 20, 2007, with respect to the objection under 35 U.S.C. 132(a), the rejection under 35 U.S.C. 112, first paragraph, and the rejection of Tobler (Patent no. 5,255,808) in view of Hurtig (Des. 267,076) have been fully considered and are persuasive. The objections and rejections of February 20, 2007 has been withdrawn.


Claims 22-42 remain pending in the instant application with claims 30, 39-42 withdrawn as directed towards a non-elected inventions: Claims 22-24, 26-29, 31-33 and 35-38 are rejected as set forth above and claims 25, 34 objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fidei whose telephone number is (571) 272-4553. The examiner can normally be reached on Monday - Thursday 6:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 2724562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David T. Fidei
Primary Examiner
Art Unit 3728

Dtf
August 22, 2007